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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/291,227	04/13/99	HAYEK M	IAM467PA

HM12/0411
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EXAMINER	
FAULKNER, D	
ART UNIT	**PAPER NUMBER**
1617	8

DATE MAILED: 04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/291,227	Hayek
Examiner	**Group Art Unit**
Faulkner, D.	1617

☒ Responsive to communication(s) filed on *Jan 31, 2000* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12, 14, and 16* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12, 14, and 16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

D Faulkner

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Declaration

1. The examiner acknowledges receipt of the amendment and response received on 1/31/00.

2. The finality of the last office action has been withdrawn, any delay in prosecution is regretful.

Claim Rejections - 35 USC § 112

The applicant's remarks have overcome the 112 rejections for crude protein.

The applicants amendment have overcome the 112 rejection for companion animals

The applicants amendment have overcome the 112 rejection for enhancing immune response and improving overall health.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jyonouchi et al, Immunomodulating actions of carotenoid: AN 1994:321921 in view of Anon, Ailment Specific dietary supplements, AN 97:19144 (both of record) further in view of CRC Handbook of Toxicology, 1995, p.11.

Jyonouchi et al describes Immunomodulating actions of carotenoid including lutein for humoral immune responses in animals. Humoral immune response include cell mediated immune responses. (See abstract) The claims differ in that Jyonouchi fails to describe the specific dietary supplements.

Anon et al describes the ailment specific dietary supplements with lutein in food products used for building stress immunity. (See title and abstract).

The claims further differ in that Jyonouchi does not teach the new limitations of the amended claims which require dogs and cats.

The CRC Handbook of Toxicology, 1995, at p.11 describes the fact that experimental animal models are known to be useful in conditions that mimic human disease.

Since Jyonouchi clearly demonstrates Immunomodulating actions of carotenoids in rats, and the CRC handbook notes that it is useful to use various animal models in order to study a disease or some other condition of interest, the ordinarily skilled artisan would have been motivated to employ a carotenoid composition found useful in invoking a immunomodulatory response in rats as similarly useful in dogs and cats. Further, it is noted that a negative animal model has not been depicted for rats and dogs and cats. Since all are mammalian animal species and well known

models in the fields of laboratory and disease research the person of ordinary skill would have found it obvious to modify the primary reference to include the supplement forms of Anon in the administration of lutein for animals, expecting the immunomodulatory response to be similarly useful in all mammals as demonstrated by Jyonouchi et al., in view of Anon and further in view of the CRC Handbook of Toxicology, 1995, absent evidence to the contrary.

The motivation for combining the references is that they are equivalent compounds which are being administered for the same reason, building immunity.

5. It is appreciated that all of the upper amounts of administration for lutein are not explicitly disclosed by the references. However it would have been obvious to the artisan to optimize amounts in order to achieve effective results. Furthermore, while certain companion animals are in Jyonouchi and Anon, i.e. mice and humans , the fact that each reference discloses that the same characteristics of lutein functioning in immune system enhancement demonstrates that the average artisan would expect lutein to have the same effect in any warm blooded animal.

6. Claims 12, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biobusiness abstract 97:19144, Anon, in view of Jyonouchi, further in view of CRC Handbook of Toxicology, 1995, p.11 as employed above.

The abstract teaches that compositions comprising lutein are known in the art. The optimization of amounts of agents to be employed is considered within the skill of the artisan. Further, the

"intended use" of a composition e.g. to improve immune response in specified animals, is not considered to further limit claims drawn to compositions. See e.g. In re Hack 114, USPQ 161.

It would have been obvious to one of ordinary skill in the art to utilize the lutein supplements of Anon in order to meet the composition as claimed by applicant The motivation for using the supplement form is that such compositions are demonstrated in the prior art.

The claims differ in that applicant has amended the claims to recite that dogs and cats are the specified animals.

The CRC Handbook of Toxicology, 1995, at p.11 describes the fact that experimental animal models are known to be useful in conditions that mimic human disease.

Since Biobusinessi clearly demonstrates lutein compositions, Jyonouchi demonstrates an increased immunomodulatory response in rats, and the CRC handbook notes that it is useful to use various animal models in order to study a disease or some other condition of interest, the ordinarily skilled artisan would have been motivated to employ a lutein (carotenoid containing) composition found useful in invoking a immunomodulatory response in rats as similarly useful in dogs and cats.

Further, it is noted that a negative animal model has not been noted for rats and dogs and cats. Since all are mammalian animal species and well known animal models in the fields of laboratory and disease research the person of ordinary skill would have found it obvious to modify the primary reference to include the supplement forms of Anon in the administration of lutein for animals, expecting the immunomodulatory response to be similarly useful in all mammals as

demonstrated by Jyonouchi et al., in view of Anon and further in view of the CRC Handbook of Toxicology, 1995, absent evidence to the contrary.

Response to Arguments

7. Applicant's arguments filed 1/31/00 have been fully considered but they are not persuasive. Applicant states that neither references teach the administration of lutein supplement to companion animals such as dogs or cats. However mammalian species are represented by Jyonouchi and are not patentably distinct from the companion animals claimed by applicant. Since lutein is effective for mammalian species as demonstrated by Jyonouchi and the CRC handbook notes the effective use of animal models in experimental modeling an immunomodulatory enhancer in rats would be presumed to be effective for all species including companion animals such as dogs and cats.

8. Applicants data has been considered, however it does not clearly demonstrate an unexpected effect for the claimed invention.

The data that applicant has presented demonstrates that immune response is greater for animals administered lutein for a period of greater than 8 weeks. The prior art teaches benefits in immune response and in several characteristics which improve the health in mammals that are fed lutein. Since the results that applicant is claiming are expected and demonstrated in the prior art, applicants data has not overcome the rejection.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Faulkner whose telephone number is (703) 305-4043. The examiner can normally be reached on Monday-Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight, III, can be reached on (703) 308-0204. The fax phone number for the organization where this application or proceeding is assigned is (703) 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JOHN KIGHT
SUPERVISORY PATENT EXAMINER
GROUP 1600

D. Faulkner

D.S.F.

February 23, 2000